510(k) Summary #K121928

FEB 19 2013

Date of Summary:	February 18, 2013
Applicant:	Caldera Medical, Inc. 5171 Clareton Drive Agoura Hills, CA 91301 P (818) 879-6555 F (818) 879-6556
Contact:	Vicki Gail QA/RA and Operations Manager P (818) 483-7602 F (818) 736-9083 E vgail@calderamedical.com
Trade Name:	Desara® SL
Device Class:	Class II
Product Code:	OTN
C.F.R Section:	21 CFR 878.3300
Common name:	Surgical Mesh, Gynecologic, For Stress Urinary Incontinence, Female
Classification Panel:	Obstetrics/Gynecology Panel
Predicate Devices:	Desara Mesh, K112609 (Primary) Gynecare TVT Abbrevo Continence System, K100936 (Secondary)

Description of Device:
Desara® SL is a sterile, single-use pubourethral 1.1 x 12cm sling used to provide support in the pelvic region to treat stress urinary incontinence or mixed incontinence. The device is manufactured out of a monofilament polypropylene yarn, which is knitted into a mesh. The device has a mid-line marker, integral sleeves, tips and sutures to assist the surgeon in placement of the device. The sleeves, tips and sutures are removed after placement of the device.

Desara® SL is designed to work with Caldera Medical's reusable transobturator helical, hook, and inside-out introducers, which utilize a Universal Connection System offering surgeons the flexibility to choose their preferred surgical approach.

Intended Use of Device:
Desara® SL is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Summary of Technological Characteristics:
The Desara SL and Desara Mesh do not have the same technological characteristics. The new technological characteristics of the Desara SL include its comparatively shorter length (12 cm versus 45 cm), and therefore, different surgical procedure. Specifically, Desara SL mesh does not exit or reach the upper thigh/groin incisions like the Desara Mesh. The upper thigh/groin incisions required are only used to adjust the mesh position during the surgical procedure. The new technological characteristics of the Desara SL could affect safety and effectiveness because the Desara SL does not extend beyond the obturator foramen like the Desara Mesh. Therefore, no tissue ingrowth or granulation will occur between the obturator foramen and upper thigh/groin incisions to provide additional support to the implant. This could affect the effectiveness of the Desara SL compared to the Desara Mesh. In regards to safety, the Desara SL requires less dissection than Desara Mesh. The new technological characteristics of Desara SL do not raise new issues of safety and effectiveness because the FDA has previously cleared a

hybrid sling, the TVT Abbrevo. TVT Abbrevo has the same length and nearly the identical implantation procedure as the Desara SL.

Performance Summary

Desara® SL is comprised of the same mesh as the predicate device, Desara® Mesh, (K112609), also a product of Caldera Medical. In accordance with the *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh,* the following mesh characteristics were assessed: mesh thickness, mesh knit characteristics, pore size, mesh density, tensile strength, mesh stiffness, flexural rigidity, tear resistance, burst strength, suture pullout and pyrogen levels.

The Desara® device was used as a reference for Desara® SL biocompatibility since both are comprised of the same materials. Desara® has passed all biocompatibility testing as indicated per the FDA guidance documents, *FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 3. Biocompatibility* and FDA *Blue Book Memorandum #G95-1 Entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".* In addition, ASTM F899-09 Standard Specification for Wrought Stainless Steels for Surgical Instruments, was referenced to support the biocompatibility of the Desara SL instrumentation.

Desara® SL instrumentation is reusable and physician labeling for the Desara SL instrumentation includes reprocessing instructions validated per the draft FDA Guidance Document *"Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued on May 2, 2011.* The reprocessing instructions for the Desara SL instrumentation are similar to those of the Desara Mini instrumentation (K103418)

Results of both mechanical bench and validation testing demonstrate equivalent device function based upon its intended use to the primary predicate device, Desara® Mesh. The following failure modes were assessed during mechanical and validation testing: sleeve to tip pull-off force, suture loop pull-out force and device mesh break strength and all testing met predefined acceptance criteria.

Testing documentation from Desara® was used to support the aging, shelf life, transportation and sterilization Desara® SL in accordance with the FDA Guidance, *Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry, FDA, FDA Device Advice, Guidance Documents (Medical Device and Radiation Emitting Product), 4. Labeling* and FDA Consensus standard, *ASTM F-1980-07, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* as it is comprised of the same materials, packaging, manufacturing and sterilization processes as that of Desara®.

One year results of the prospective randomized trial by de Leval J, et al[1] found that at one year follow-up a modified inside-out transobturator tape procedure utilizing a 12 cm sling or 'tape' length like Desara SL was as safe and efficacious as the original transobturator technique but associated with less immediate post-operative groin pain.

Summary of Substantial Equivalence

The conclusions drawn from the non-clinical and clinical tests demonstrate that the Desara SL is substantially equivalent to its proposed predicate devices.

[1] de Leval, J, Waltregny TD. The original versus a modified inside-out transobturator procedure: 1-year results of a prospective randomized trial. Int Urogynecol J (2011) 22:145-156. DOI 10.1007/s00192-010-1264-4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 19, 2013

Caldera Medical, Inc.
% Ms. Vicki Gail
QA/RA Manager
5171 Clareton Drive
AGOURA HILLS CA 91301

Re: K121928
Trade/Device Name: Desara SL
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: January 29, 2013
Received: January 31, 2013

Dear Ms. Gail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121928

Device Name: Desara SL

Indications for Use:

Desara SL is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Prescription Use	[x]	AND/OR	Over-The-Counter Use	[ ]
(21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121928